

DECLARATION OF BLOOD PRESSURE MEASURING DEVICE EQUIVALENCE 2006

A SIGNED COPY WILL BE POSTED ON THE www.dableducational.org WEBSITE

SECTION A - Please complete all items online.

I Albert Lee Director of Health & Life Co., Ltd.
Name of a Company Director Company name

hereby state that there are no differences that will affect blood pressure measuring accuracy between the

Beurer BM35
Blood pressure measuring device for which validation is claimed

blood pressure measuring device and the

HL868BA
Existing validated blood pressure measuring device

blood pressure measuring device, which has previously passed the ESH protocol, the results of which were published as follows

Han-E Chen, Yan Cui, Chang-Sheng, Li-Hua Li, Yan Li, Ji-Guang Wang
Authors(s)

Validation of the Healthy & Life HL868BA blood pressure monitor for home blood pressure

Monitoring according to the European Society of Hypertension International Protocol

Wolter Kluwer Health/Lippincott Williams & Wilkins 2008, Vol 13 No 5, Page 305-308
Publication Year Volume Pages

The only differences between the devices involve the following components:

(When a component is not relevant, both Yes and No should be left blank. Please provide details on any differences below.)

Part I	1	Algorithm for Oscillometric Measurements	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	2	Algorithm for Auscultatory Measurements	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	3	Artefact/Error Detection	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	4	Microphone(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	5	Pressure Transducer	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	6	Cuff or Bladder	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	7	Inflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	8	Deflation Mechanism	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Part II	9	Model Name or Number	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	10	Casing	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	11	Display	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	12	Carrying/Mounting Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	13	Software other than Algorithm	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	14	Memory Capacity/Number of stored measurements	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	15	Printing Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	16	Communication Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
	17	Power Supply	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
	18	Other Facilities	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>

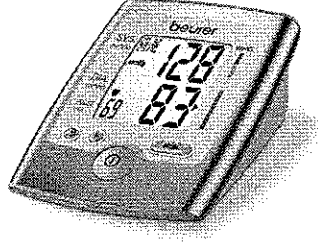
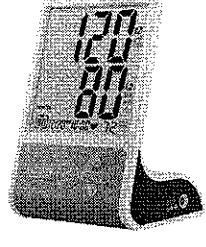
Brief explanation of differences and further relevant details:

The differences between the modules are the unit dimension, external casing, display LCD size, amounts of button, amounts of memory, and type of battery. However, these differences do not affect the measurement algorithm and clinical performance.

SECTION B - Complete all items, bar signatures and seal, online and print. Sign and seal it then send the original along with manuals for both devices to our address below.

Signature of Director Albert Lee Company Stamp/Seal
Name Albert Lee
Date November 26 2010
Signature of Witness Bill Wang
Name Bill Huang
Address 9F, No 186, Jian Yi Road, Chung Ho City, Taipei, Taiwan

Comparison of submitted device to validated device:




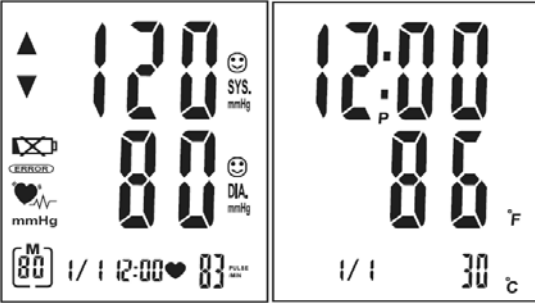
	Submitted device (1)	Validated device (2)
Devices	Beurer BM35	HL868BA
Images		
Validation		ESH International Protocol Pass
Same Criteria		
Measurement method	Oscillometric measurement	Oscillometric measurement
Operating ambient	10°C ~40°C, ≤ 85%R.H.	10°C ~40°C, ≤ 85%R.H.
Storage ambient	-20°C~70°C, ≤ 85%R.H.	-20°C~70°C, ≤ 85%R.H.
Measurement range of blood pressure	40~280 mmHg	40~280 mmHg
Accuracy range of blood pressure	±3 mmHg	±3 mmHg
Measurement range of pulse	40~199 beats/min.	40~199 beats/min.
Accuracy range of pulse	±5%	±5%
Unit display	mmHg	mmHg
ERROR indication	Yes	Yes
Low battery detect	4.3~4.9V	4.3~4.9V
Battery using time	≥ 300 times(twice a day measurement)	≥ 300 times(twice a day measurement)
Deflation time	12~30 sec.	12~30 sec.
Deflation rate of air leakage	2~5 mmHg/sec.	2~5 mmHg/sec.
Specification of pressure sensor	Semiconducting pressure sensor	Semiconducting pressure sensor
Specification of air pump	6V DC Motor	6V DC Motor
Type of exhaust valve	Automatic exhaust valve	Automatic exhaust valve
Dimension of cuff	Normal cuff 9" ~ 13"	Normal cuff 9" ~ 13" Large cuff 13" ~ 17"
Irregular Heartbeat Detector (IHB)	Yes	Yes
Comparable Criteria		

Power source (battery) type	DC 6 V ("AAA"1.5V alkaline battery x4)	DC 6 V ("AA"1.5V alkaline battery x4)
Unit dimension(Exclude cuff)	135 mm (L) x105 mm (W) x53 mm (H)	111 mm(L) x 100 mm(W) x 183 mm(H)
Specification of LCD	66.5 mm (L) × 55 mm (W) × 2.8 mm(H)(60 × 51 mm LCD in reality) TN, Reflective, Positive, 4.4V	112.5 mm(L) x 99 mm(W) x 2.8 mm(H) (105 x 94 mm LCD in reality) TN, Transparent, Positive, 4.4V
Memories(Person x Sets)	2 x 60	3 x 80
Time display	24hr	12hr, LCD always on (stand-by)
Key quantities	4 keys (Start/Stop, MEM, Time, +)	5 keys (Start/Stop, Memory, Mode, Up, Down)
Average display	All data averaging (ALL , AM (05:00 ~ 09:00) , PM(17:00 ~ 21:00))	Last 3 memories
Self-management	No	Yes
Temperature detect / Accuracy	No	Yes / ±2 °C
WHO classification	Yes	No
External power source (adaptor)	No	Linear type adaptor
Comment	The Beurer BM35 and HL868BA use the same measurement method to get blood pressure result. Those differences do not affect the measurement algorithm and clinical performance.	
Recommendation	Accept	

Approved by:

Bill Lim 2010.11.26

Comparison of the Beurer BM35 with the Health and Life HL868BA

Devices	Beurer BM35	Health and Life HL868BA
Pictures		
Display		
Validation		ESH
Device 1 Criteria	<p>Display/Symbols/Indicators</p> <p><i>Analysis</i></p> <p>Average: AVG 10</p> <p>Morning/Evening mean: AVG with R (am) or P (pm) 10</p> <p>Algorithms</p> <p><i>Averages</i></p> <p>All measurements mean values 13</p> <p>7-day morning and evening mean values 13</p>	
Same Criteria	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy or ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p>	<p>Measurement</p> <p><i>Accuracy</i></p> <p>BP accuracy ± 3 mmHg 1, 5</p> <p>Pulse accuracy or ± 5% 1, 5</p> <p><i>Method</i></p> <p>Oscillometric measurement method 1, 5</p>

Devices	Beurer BM35	Health and Life HL868BA
Same Criteria (continued)	<p>Measurement (continued)</p> <p><i>Method</i></p> <p>BP 40 mmHg - 280 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -199 bpm 1, 5</p> <p><i>Inflation</i></p> <p>Zero pressure check before inflation ^{Query 2} 7</p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Sensors</i></p> <p>Pressure sensor: semi conductor* 5</p> <p><i>Cuffs</i></p> <p>Medium (Arm circ. 23 to 33 cm) 6</p> <p>Buttons/Switches</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol during deflation 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Irregular heartbeat 11, 13</p> <p><i>Measurement Records</i></p> <p>Memory 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Settings</i></p> <p>Unit Symbol (mmHg) 10</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p>Case</p> <p><i>Display</i></p> <p>Single screen display 10</p>	<p>Measurement (continued)</p> <p><i>Method</i></p> <p>BP 40 mmHg - 280 mmHg 1, 5, 7, 8</p> <p>Pulse 40 bpm -199 bpm 1, 5</p> <p><i>Inflation</i></p> <p>Zero pressure check before inflation ^{Query 2} 7</p> <p>Inflation 0 mmHg - 300 mmHg 1, 5, 7</p> <p>Automatic Inflation 7</p> <p><i>Deflation</i></p> <p>Automatic Deflation 8</p> <p><i>Sensors</i></p> <p>Pressure sensor: semi conductor* 5</p> <p><i>Cuffs</i></p> <p>Medium (Arm circ. 23 to 33 cm) 6</p> <p>Buttons/Switches</p> <p><i>Measurement Records</i></p> <p>Memory 10</p> <p>Display/Symbols/Indicators</p> <p><i>Measurement Procedure</i></p> <p>Heartbeat symbol during deflation 11</p> <p><i>Post Measurement</i></p> <p>SBP, DBP and Pulse 11</p> <p>Irregular heartbeat 11, 13</p> <p><i>Measurement Records</i></p> <p>Memory 11</p> <p><i>Date and Time</i></p> <p>Date and Time 11</p> <p>Date and Time (During memory recall) 11</p> <p><i>Settings</i></p> <p>Unit Symbol (mmHg) 10</p> <p><i>Power</i></p> <p>Low battery 11, 17</p> <p>Algorithms</p> <p><i>Diagnostic</i></p> <p>Irregular heartbeat detection 13</p> <p>Case</p> <p><i>Display</i></p> <p>Single screen display 10</p>

Devices	Beurer BM35	Health and Life HL868BA
Same Criteria (continued)	Case (continued) <i>Power</i> Automatic switch-off when not used for 1 min 17	Case (continued) <i>Power</i> Automatic switch-off when not used for 1 min 17
Comparable Criteria	Measurement <i>Post Measurement</i> Measurement error (Error numbers E1 E2 E3 EE) ^{Query 1} 11 <i>Measurement Records</i> Memory: 60 measurements × 2 zones 14 Buttons/Switches <i>Power</i> On/Off with Start/Stop (symbol label) 10 <i>Settings</i> Function and Adjust (+ symbol) 10 Display/Symbols/Indicators <i>Post Measurement</i> BP classification (WHO) 10, 11, 13 Algorithms <i>Diagnostic</i> WHO Guidelines 13 Case <i>Power</i> 4 “AAA” batteries ~ 250-300 measurements 17	Measurement <i>Post Measurement</i> Measurement error (symbol only - no error numbers) 11 <i>Measurement Records</i> Memory: 80 measurements × 3 zones 14 Buttons/Switches <i>Power</i> Start/Stop (symbol label, standby shows temperature) 10 <i>Settings</i> Mode, up and down 10 Display/Symbols/Indicators <i>Post Measurement</i> BPs flash if HBP, ☺ symbol if BP OK 11, 13 Algorithms <i>Diagnostic</i> Self diagnosis (Set thresholds) 10, 11, 13 Case <i>Power</i> 4 “AA” batteries ~ 300 measurements 17
Device 2 Criteria		Measurement <i>Method</i> Optional repeated measurements (3 or 5) – median used 13, 14 <i>Cuffs</i> Large (Arm circ. 33-43 cm) 6 Display/Symbols/Indicators <i>Measurement Procedure</i> Inflation symbol 11 Deflation symbol 11 <i>Measurement Records</i> Memory recall number 11 <i>Features</i> Ambient temperature 11 Algorithms <i>Averages</i> Last 3 measurements mean 13

Devices	Beurer BM35	Health and Life HL868BA
Device 2 Criteria (continued)		<p>Algorithms (continued)</p> <p><i>Averages</i></p> <p>Three and five measurements median (multi-measurement) 13</p> <p>Case</p> <p><i>Power</i></p> <p>AC adapter (Optional) 17</p> <p>Rechargeable batteries permitted 17</p>
Web link	http://www.beurer.com/web/en/product/blood_pressure/upper_arm/detail.php?pk=31&id=12827&bek=112&bct=%26nbsp%3B%26gt%3B%26nbsp%3Bproduct+details%26nbsp%3B%26gt%3B%26nbsp%3BBM35	None available
Comments	<p>* Not in the manual but supplied on data sheets</p> <p>Health & Life is an OEM manufacturer for the BM35.</p> <p>Note 1 Though not in the manual, two cuff sizes for the HL868BA, for arm circumferences in the ranges 23-33 cm and 33-43 cm, are available.</p> <p>Response <i>The additional cuff is just a spare part, but you are right it should be mentioned in the manual. We've made an update of the manual, including the bigger cuff 33-34cm.</i></p> <p>Query 1 Error Codes E1, E2 and E3 and EE are described in the manual for the BM35. No error codes are described for the HL868BA. Are the same codes generated for the HL868BA?</p> <p>Response 1 <i>The HL868BA Error icon is including BM35 E1, E2 , E3 and EE, but it does not show the different Error codes .</i></p> <p>Query 2 Is the zero pressure check used in the HL868BA?</p> <p>Response 2 <i>Yes, zero pressure check is used in the HL868BA</i></p>	
Recommendation	Equivalence is Recommended	
Date	31/01/2011	